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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,382	06/15/2001	Wan S. Lee	1408.017	8310

23405 7590 03/26/2003

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/882,382	Applicant(s) LEE ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' priority papers and preliminary amendment A, both filed 06/15/2001; preliminary amendment B and IDS, both filed 09/17/2001; and supplemental IDS, filed 11/18/2002.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,035,894 ('894).

The instant claim 1 recites a transdermal preparation having an adhesive layer comprising a hydrophilic drug or drug in the salt form and an adhesive has polyethylene oxide or polyethylene oxide monomethyl ether side chain.

US '894 disclosed a transdermal drug delivery device incorporating an adhesive composition comprising grafted polymer includes polyethylene oxide side chains which impart increased solubility of hydrophilic bioactive agents in the polymer matrix, thus, enhances the rate of release of the rate of release of the bioactive agents (abstract; col.3, lines 8-12, 23). The molecular weight of the polyethylene oxide ranges between 10-1000 with a range of 100-55 preferred (col.5, lines 6-11, 61-66). The drug used included hydrocortisone and antihistaminics in an amount up to at least 10 wt% of the adhesive composition (col.8, lines 48-50, 62-63).

The limitations of claims 1 and 3 are met by US '894 reference.

4. Claims 1, 2, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,779,632 ('632).

US '632 disclosed a pressure sensitive adhesive used for transdermal pharmaceutical delivery devices comprising polyethylene oxide acrylates, disclosed by applicant in page 7, lines 1-2 as an adhesive having polyethylene oxide side chain, and any therapeutic active agent useful in transdermal delivery devices or salts of those drugs (abstract; col.10, lines 35-41; col.31, line 34; col.32, line 1). The pressure sensitive adhesive further comprising a solvent and a penetration enhancer that included oleic acid and isopropyl myristate (col.32, lines 7-20). The reference disclosed a dosage form comprising a layer of the pressure sensitive adhesive coated on a backing layer and protected with a release liner (col.31, lines 40-44).

The limitation of claims 1, 2, 16, and 17 are met by US '632 reference.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2, 4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '894 in view of US 5,865,792 ('792).

US '894 teaches a transdermal drug delivery device incorporating an adhesive composition comprising grafted polymer includes polyethylene oxide side chains which impart increased solubility of hydrophilic bioactive agents in the polymer matrix, thus, enhances the rate of release of the rate of release of the bioactive agents (abstract; col.3, lines 8-12, 23). The molecular weight of the polyethylene oxide ranges between

10-1000 with a range of 100-55 preferred (col.5, lines 6-11, 61-66). The drug used included hydrocortisone and antihistaminics in an amount up to at least 10 wt% of the adhesive composition (col.8, lines 48-50, 62-63).

US '894 does not teach the solvent of and the penetration enhancer of claims 2 and 7-9, any particular salt of the drug as claimed in claims 6 and 13, or the amount of the solvent, penetration enhancer and the polyethylene oxide.

US '792 teaches a device for transdermal drug delivery comprising polymeric reservoir comprising anti-inflammatory agent, solvent and penetration enhancer (abstract; col.10, line 15). The preferred anti-inflammatory agent that eliminates tissue irritation is hydrocortisone succinate (col.2, lines 50-52; col. 3, lines 13-15). The solvent includes ethanol, isopropanol, glycols such as polyethylene glycol and polypropylene glycol, and sorbitan fatty acid esters that disclosed by applicants as penetration enhancer (col.7, lines 24-33). The polymer includes polyethylene oxide blended with polyacylic acid (col.9, lines 22-31).

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the solvent, the polyethylene oxide and the penetration enhancer instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to select the hydrocortisone succinate and the suitable solvent and penetration enhancers as disclosed by US '792 to be included in the adhesive

composition of a transdermal drug delivery device disclosed by US '894 and determine the amount of each ingredient according to particular need, motivated by the teaching of US '792 that the hydrocortisone succinate is the preferred anti-inflammatory drug that eliminates tissue irritation with reasonable expectation of success of the delivered transdermal drug delivery device in providing drugs in the salt forms in a controlled release manner.

8. Claims 3, 6-11, and 13-15, rejected under 35 U.S.C. 103(a) as being unpatentable over US '632 in view of US '792.

US '632 teaches a pressure sensitive adhesive used for transdermal pharmaceutical delivery devices comprising polyethylene oxide acrylates, disclosed by the applicant in page 7, lines 1-2 as an adhesive having polyethylene oxide side chain, and any therapeutic active agent useful in transdermal delivery devices or salts of those drugs (abstract; col.10, lines 35-41; col.31, line 34; col.32, line 1). The pressure sensitive adhesive further comprising a solvent and a penetration enhancer that included oleic acid and isopropyl myristate (col.32, lines 7-20). The reference disclosed a dosage form comprising a layer of the pressure sensitive adhesive coated on a backing layer and protected with a release liner (col.31, lines 40-44).

US '632 does not teach the particular salts of the drugs as claimed in claims 6 and 13, the particular solvents of claims 7, or the amount of the drug, solvent and the penetration enhancer.

US '792 teaches a device for transdermal drug delivery comprising polymeric reservoir comprising anti-inflammatory agent, solvent and penetration enhancer (abstract; col.10, line 15). The preferred anti-inflammatory agent that eliminates tissue irritation is hydrocortisone succinate (col.2, lines 50-52; col. 3, lines 13-15). The solvent includes ethanol, isopropanol, glycols such as polyethylene glycol and polypropylene glycol, and sorbitan fatty acid esters that disclosed by applicants as penetration enhancer (col.7, lines 24-33). The polymer includes polyethylene oxide blended with polyacylic acid (col.9, lines 22-31).

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the drug, the solvent, and the penetration enhancer instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to select the hydrocortisone succinate as the drug salt and the suitable solvent as disclosed by US '792 to be included in the adhesive composition of a transdermal drug delivery device disclosed by US '632 and determine the amount of each ingredient according to particular need, motivated by the teaching of US '792 that the hydrocortisone succinate is the preferred anti-inflammatory drug that eliminates tissue irritation with reasonable expectation of success of the delivered transdermal drug delivery device in providing drugs in the salt forms in a controlled release manner.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali